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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health

[Announcement Number 521]

Occupational Radiation and Energy-Related Health Research Grants; Notice of Availability of Funds for Fiscal Year 1995

Introduction

The Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), announces that applications are being accepted for research projects relating to occupational safety and health concerns associated with occupational exposures to radiation and other hazardous agents at nuclear facilities and in other energy-related industries. Studies in the nuclear power industry and deliberate exposure of human subjects in radiation experiments are outside the scope of this announcement.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Occupational Safety and Health. (For ordering a copy of "Healthy People 2000," see the section "Where to Obtain Additional Information.")

Authority

This program is authorized under the Public Health Service Act, as amended, Section 301(a) (42 U.S.C. 241(a)) and the Occupational Safety and Health Act of 1970, Section 20(a) (29 U.S.C. 669(a)). The applicable program regulations are in 42 CFR Part 52.

Eligible Applicants

Eligible applicants include domestic and foreign non-profit and for-profit organizations, universities, colleges, research institutions, and other public

and private organizations, including State and local governments and small, minority and/or woman-owned businesses.

Smoke-Free Workplace

The Public Health Service strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. This is consistent with the PHS mission of promoting the protection and advancement of an individual's physical and mental health.

Availability of Funds

Approximately \$500,000 is available in FY 1995 to fund approximately 3 to 5 research project grants (R01). The amount of funding available may vary and is subject to change. Awards will range from \$25,000 to \$200,000 in total costs (direct and indirect) per year. Awards are expected to begin on or about September 1, 1995. Awards will be made for a 12-month budget period within a project period not to exceed 3 years. Continuation awards within the project period will be made on the basis of satisfactory progress and availability of funds.

Purpose

NIOSH will support applied field research projects to identify and investigate the relationships between health outcomes and occupational exposure to radiation and other hazardous agents; epidemiologic methods research relevant to energy-related occupational health research; and research related to assessing occupational exposures.

Programmatic Interest

The focus of grants should reflect the following topical areas, emphasizing field research: (1) Occupational exposure assessment, (2) radiation measurement issues, (3) non-cancer morbidity and mortality outcomes, (4) meta-analysis and combined analysis methodologies, (5) uncertainty analysis, (6) effects of measurement error on risk estimates, and (7) studies of current workers.

(1) Retrospective Exposure Assessment

Epidemiologic studies of occupational cohorts frequently involve, and can generally benefit from, retrospective exposure assessment to provide estimates of exposure or categorize groups of workers by common exposure. Exposure assessment in energy-related occupational epidemiology requires evaluating exposures to various hazards including ionizing and non-ionizing radiation, metals, acids, and solvents.

Grant opportunities encompass the fields of industrial hygiene and retrospective exposure assessment of health physics dosimetry. Research areas of general interest include: Methods to use limited data to best advantage; how to treat censored data in retrospective exposure assessment; uncertainty analysis techniques for industrial hygiene exposure data and health physics dosimetry; insight to sampling strategy design yielding a representative understanding of exposed groups; decision logic to select/use the most appropriate exposure metric for epidemiologic and risk assessment use; and, development approaches of "Homogeneous Exposed Groupings" and the advantages/limitations for epidemiologic use. Research opportunities of specific interest include: reconstruction and dose adjustment of historic film badges; exposure assessment for acid mists, carcinogenic solvents, exotic metals, and leukemogens; assessment of electromagnetic field exposure; and evaluation of biomarkers of exposure.

(2) Radiation Measurement Issues

This topic will focus on the applicability and utility of radiation dose data in epidemiological research. Examples of such issues include how to use nondetectable values and missing dose data in historical radiation exposure measurements, the accuracy of historical external dosimetry techniques (film and pocket dosimeters), combining external and internal doses into a useful index, historical bioassay, and radiochemistry techniques.

(3) Non-cancer Morbidity and Mortality Outcomes

The majority of analytical epidemiologic research of health effects of energy-related occupational and environmental exposures has focused historically on the assessment of the association between cancer mortality and exposure to ionizing radiation. Although the importance of this research should not be underestimated, it is essential that other potential adverse health effects, as well as other possible energy-related exposures, be thoroughly evaluated as well. Among these would be the possible effects of radiation on the reproductive, neurologic, and immune systems. Chemical exposures highly prevalent in Department of Energy facilities, such as beryllium and mercury, have also been associated with a variety of disease outcomes, particularly respiratory and neurologic in nature.

(4) *Meta-Analysis and Combined Analysis Methodologies*

Many of the cohorts at nuclear facilities are not individually large enough to detect statistically significant increases in mortality or incidence for rare cancer types. Methods and/or analyses for combining data across studies, whether in summary form or individual data, are valuable to the NIOSH research effort involving energy-related health research.

(5) *Uncertainty Analysis*

Measures of occupational exposure are inherently uncertain. Even when measures of external radiation exposure are generally available, the models, used to estimate organ dose, shallow versus deep dose, neutron dose, etc., are subject to error. Measures of dose derived from biological monitoring of urine, feces, blood, etc., are even less precise. Methods for assessing the degree of error in various estimates of exposure to both ionizing radiation as well as other toxic agents (chemicals, EMF, etc.) are desirable.

(6) *Effects of Measurement Error on Risk Estimates*

Estimation of both bias and imprecision introduced into risk analyses through exposure measurement error have recently received considerable attention. Many of the suggested approaches are very computer intensive. Practical solutions to this problem with regard to the spectrum of epidemiologic designs (cohort, case-control, cross-sectional, etc.) are needed, with particular attention to the nature of exposure measurement in radiation epidemiology.

(7) *Studies of Current Workers*

Much of the epidemiologic research on nuclear workers conducted at nuclear facilities and other sites has emphasized retrospective studies. More recently new activities involve environmental restoration, waste management and other work that is not related to the design and production of nuclear weapons. Workers are being exposed to radiation and other hazardous agents under conditions and in processes not previously encountered. Exposure assessment, epidemiologic and related studies are needed to evaluate these new conditions and processes and the impact on worker health.

Inclusion of Minorities and Women in Study Populations

Applicants are required to give added attention (where feasible and appropriate) to the inclusion of

minorities and/or women study populations for research into the etiology of diseases, research in behavioral and social sciences, clinical studies of treatment and treatment outcomes, research on the dynamics of health care and its impact on disease, and appropriate interventions for disease prevention and health promotion. Exceptions would be studies of diseases which exclusively affect males or where involvement of pregnant women may expose the fetus to undue risks. If minorities and/or women are not included in a given study, a clear rationale for their exclusion must be provided.

Evaluation Criteria

Upon receipt, applications will be reviewed for completeness and responsiveness by NIOSH. Incomplete applications will be returned to the applicant without further consideration. If NIOSH staff finds that the application is not responsive to this announcement, it will be returned without further consideration. If the proposed project involves organizations or persons other than those affiliated with the applicant organization, letters of support and/or cooperation must be included.

Applications that are complete and responsive to this announcement will be evaluated for scientific and technical merit by an appropriate peer review group convened by the CDC in accordance with the review criteria stated below. As part of the initial merit review, a process (triage) may be used by the initial review group in which applications will be determined to be competitive or non-competitive based on their scientific merit relative to other applications received in response to this announcement. Applications judged to be competitive will be discussed and be assigned a priority score. Applications determined to be non-competitive will be withdrawn from further consideration and the principal investigator/program director and the official signing for the applicant organization will be promptly notified.

Review criteria for this announcement is the same as those for unsolicited research grant applications:

- Scientific, technical, or medical significance and originality of proposed research;
- Appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research;
- Qualifications and research experience of the Principal Investigator and staff, particularly but exclusively in the area of the proposed research;

- Availability of resources necessary to perform the research;
- Adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

The review group will critically examine the submitted budget and will recommend an appropriate budget and period of support for each scored application.

In the secondary (programmatic importance) review, the following factors will be considered:

1. Results of the initial review;
2. Magnitude of the problem in terms of numbers of workers affected;
3. Severity of the disease or injury in the worker population; and
4. Usefulness to applied technical knowledge in the identification, evaluation, and/or control of occupational safety and health hazards.

Applicants will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

1. Quality of the proposed project as determined by peer review;
2. Availability of funds; and
3. Program balance among research areas of the announcement.

Executive Order 12372—Review

Applications are not subject to the review requirements of Executive Order 12372, entitled Intergovernmental Review of Federal Programs.

Public Health System Reporting Requirement

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.262.

Other Requirements

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR part 46) regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate

guidelines and form provided in the application kit.

Application Submission and Deadlines

A. Preapplication Letter of Intent

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter should be submitted to the Grants Management Officer (whose address is reflected in section B, "Applications"). It should be postmarked no later than March 15, 1995. The letter should identify the announcement number, name of principal investigator, and specify the priority area to be addressed by the proposed project. The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently, and will ensure that each applicant receives timely and relevant information prior to application submission.

B. Applications

Applicants should use Form PHS-398 (OMB Number 0925-0001) and adhere to the ERRATA Instruction Sheet for Form PHS-398 contained in the Grant Application Kit. Please submit an original and five copies on or before April 19, 1995 to: Henry S. Cassell, III, Grants Management Officer, Procurement and Grants Office, Centers for Disease Control and Prevention, (CDC), 255 East Paces Ferry Road, NE., Room 300, MS-E13, Atlanta, GA 30305.

C. Deadlines

1. Applications shall be considered as meeting a deadline if they are either:

A. Received at the above address on or before the deadline date, or

B. Sent on or before the deadline date to the above address, and received in time for the review process. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be accepted as proof of timely mailings.

2. Applications which do not meet the criteria above are considered late applications and will be returned to the applicant.

Where To Obtain Additional Information

All application procedures and guidelines are contained within the present announcement. Business management information may be obtained from Lisa G. Tamaroff, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., MS-E13, Atlanta,

GA 30305, telephone (404) 842-6796. Programmatic technical assistance may be obtained from Roy M. Fleming, Sc.D., Associate Director for Grants, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Building 1, Room 3053, MS-D30, Atlanta, GA 30333, telephone (404) 639-3343.

When requesting information, please refer to announcement number 521.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report, Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 783-3238.

Dated: January 18, 1995.

Linda Rosenstock,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).

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[CDC-510]

Announcement of Cooperative Agreement to the United States Conference of Mayors

Summary

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1995 funds for a sole source cooperative agreement with the United States Conference of Mayors (USCM) to continue supporting: an information exchange program among mayors and other local and State government officials concerning HIV prevention; HIV prevention program and policy development; and the provision of technical and financial assistance to community-based organizations (CBOs), local and State health departments, and others involved in health promotion and disease prevention activities.

Approximately \$2,000,000 will be available in FY 1995 to support this project, though the funding estimate may change. This award will begin on or about May 1, 1995, for a 12 month budget period within a 5 year project period. Continuation awards within the project period will be made if progress is satisfactory and funds are available.

The CDC will assist in identifying programs, policies, practices, procedures, and processes pertinent to the program objectives; collaborate in developing, analyzing, and presenting material for information dissemination;

review and comment on all HIV-related materials intended for dissemination; and assist in identifying community planning groups in need of fiscal support.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of HIV Infection. (For ordering a copy of "Healthy People 2000," see the section "Where to Obtain Additional Information.")

Authority

This program is authorized under the Public Health Service Act: Sections 301(a) [42 U.S.C. 241(a)], as amended; and 317 [42 U.S.C. 247b], as amended.

Smoke-Free Workplace

The Public Health Service strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Eligible Applicant

Assistance will be provided only to the USCM. No other applications are solicited. The program announcement and application kit have been sent to USCM. Eligibility is limited to USCM since it provides representation from city and local officials, including social services, education, and other community officials and organizations, in approximately 1,000 cities with populations of more than 30,000 and, through its affiliate the United States Conference of Local Health Officials, provides representation from approximately 2,000 additional local health officials. USCM was created specifically to represent this wide variety of local organizations and community officials to the Federal government and other national organizations and is unique in its role as a liaison between these officials. It has served as a policy-development and capacity-building organization in intergovernmental affairs for more than 60 years and has as one of its major objectives the sharing of information between local governments.

USCM has established a unique HIV prevention program that brings together, at the local level, the key players responding to the Acquired Immune Deficiency Syndrome (AIDS) crisis: mayors, local health department (LHD)